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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,019	02/07/2001	Mark William Doane	0100/0090	6226

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EXAMINER

MITCHELL, TEENA KAY

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 05/23/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/778,019	DOANE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Teena K Mitchell	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4,5</u> | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of Invention 1 claims 1-7, 10, and 11 in Paper No. 8 is acknowledged.

***Specification***

The disclosure is objected to because of the following informalities: Page 4 last line, "...machine end 22..." should be amended to read --machine end 12-- as previously disclosed.

Correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 3, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Brain (5,305,743).**

Brain in a mask discloses a soft cuff member (13), said cuff member being of substantially annular shape (Figs. 1, 2, 2A); and a rigid mount member (12), said mount member being more rigid than said cuff member (13) and being of generally funnel shape (Fig. 1), and wherein said cuff member is molded with said mount member (Col. 2, lines 67, 68 and Col. 3, lines 1-34).

With respect to claim 3, Brain discloses wherein said cuff member (13) and mount member (12) are molded integrally as a single piece (Col. 2, lines 67, 68 and Col. 3, lines 1-34).

With respect to claim 5, Brain discloses wherein said cuff member is hollow (13).

With respect to claim 6, Brain discloses wherein said mask is a laryngeal mask (Abstract) and said cuff member is adapted to seal with tissue in the region of the hypopharynx (Col. 9, lines 48-58) and it is inherent and well-known in the art that a laryngeal mask cuff is adapted to seal with tissue in the region of the hypopharynx which provides the needed seal.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 2, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brain (5,305,734) in view of Shibata (JP409216240A).**

The difference between Brain and claim 2 is wherein said cuff member is formed by rotational molding.

Shibata in a mask teaches a mask cushion formed by rotational molding (Abstract).

It would have been obvious to one of ordinary skill in the art to modify the molding of Brain to employ any well-known rotational molding doing so would have provided a convenient and cost effective method including the rotational molding taught by Shibata.

With respect to claim 10, Shibata teaches rotational molding (Abstract).

With respect to claim 11, Shibata teaches rotational molding (Abstract)

**Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brain (5,305,743).**

The difference between Brain and claim 4 is the mount member pre-formed and the cuff member molded with said mount member. Brain discloses a cuff member (13) and a mount member (12). Brain does not disclose the mount member pre-formed and the cuff member molded to the mount member. Applicant has not disclosed that having the mount member pre-formed and the cuff member molded to the mount member solves any stated problem or is for any particular purpose. Moreover, it appears that whether the mount member is pre-formed and molded to the cuff member the mask would perform equally well to seal the hypopharynx. Accordingly, having the mount member preformed and the cuff member molded to the mount member is deemed to be a design consideration, which fails to patentably distinguish over the prior art of Brain.

**Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brain (5,305,743) in view of Sullivan et.al. (5,243,971).**

The difference between Brain and claim 7 is wherein said mask is a facemask.

Sullivan teaches a face mask (19) having a soft cuff member (13) and a mount member (24) molded with said mount member (Col. 2, lines 50-67) providing a self-conforming mask which by overlaying and conforming to the shape to the wearer provides an inherently large self-sealing area and can be used to seal around the nose and mouth of a user (Col. 2, lines 45-49 and Col. 4, lines 12-23).

It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the laryngeal mask of Brain to employ any well-known face mask doing so would have provided a self-conforming mask which by overlaying and conforming to the shape to the wearer provides an inherently large self-sealing area and can be used to seal around the nose and mouth of a user including the face mask taught by Sullivan.

### ***Conclusion***

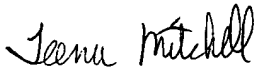
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show mask with cuff and mount members.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena K Mitchell whose telephone number is (703) 308-4016. The examiner can normally be reached on Monday-Friday during normal business hours.

Art Unit: 3761

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Teena Mitchell  
Patent Examiner  
Art Unit 3761  
May 18, 2003